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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,543	02/08/2002	Kevin B. Morton	NEOMTRX.4C1DV2	4228

20995 7590 05/19/2008
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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

NOTIFICATION DATE	DELIVERY MODE
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05/19/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No. 10/072,543	Applicant(s) MORTON ET AL.	
	Examiner JONATHAN ML FOREMAN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

New grounds of rejection are contained within this Office Action. Accordingly this action has been made Non-Final.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 13 – 16, 18, 23 – 28, 30, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,273,868 to Nordvik in view of US Patent No. 5,733,319 to Neilson et al.

In regards to claims 13 – 16, 18, 23 – 28, 30, 35 and 36, Nordvik discloses a closed loop system (Figure 3) including at least three inflatable bladders (13 – 16) configured to provide circumferential compressive force adjacent a lactiferous sinus of a breast for the purpose of expressing intraductal fluid; a reservoir (19), and a fluid flow path (17, 18), where the system can be operated and removed without exposing the closed loop to the outside of the system. A heat exchange fluid is contained within the closed loop (Col. 6, lines 54 – 55). However, Nordvik fails to disclose the fluid flow path including an inflow line and an outflow line for placing the bladders in fluid communication with the reservoir nor a movable wall such that the fluid in the system can be moved by application of external pressure to the moveable wall. However, Neilson et al. discloses a closed loop system including an inflow line (94A) and an outflow line (96A) for placing a bladder in fluid communication with a compressible reservoir (110; Col. 8, line 40) and being free of a pump,

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wherein the closed loop system can be operated and removed without exposing a fluid within the closed loop system to the outside of the closed loop system (Col. 6, lines 15 – 20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the closed loop system as disclosed by Nordvik to include an inflow line and an outflow line, a compressible container and to be free of a pump, wherein the closed loop system can be operated and removed without exposing a fluid within the closed loop system to the outside of the closed loop system as taught by Neilson et al. in order to allow the closed loop system to be disposable to thereby eliminate otherwise necessary cleaning and sterilization of non-disposable, fixed heat transfer units (Col. 6, lines 15 – 20).

3. Claims 19 – 22 and 31 - 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,273,868 to Nordvik in view of US Patent No. 5,733,319 to Neilson et al.

In regard to claims 19 – 22 and 31 – 34, Nordvik in view of Neilson et al. fail to disclose the inflated width, length or thickness of the bladders. However, a change in the size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inflated width, length or thickness to be any size as desired in order to allow for use by women having different size breasts.

4. Claims 1 – 4, 6, 8 - 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,273,868 to Nordvik in view of US Patent No. 5,733,319 to Neilson et al.

In regards to claims 1 – 4, 6, 8 - 12, Nordvik discloses a closed loop system (Figure 3) including at least three inflatable bladders (13 – 16) configured to provide circumferential compressive force adjacent a lactiferous sinus of a breast for the purpose of expressing intraductal fluid; a reservoir (19), and a fluid flow path (17, 18), where the system can be operated and removed without

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exposing the closed loop to the outside of the system. A heat exchange fluid is contained within the closed loop (Col. 6, lines 54 – 55). Nordvik fails to disclose the inflated width, length or thickness of the bladders. However, a change in the size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inflated width, length or thickness to be any size as desired in order to allow for use by women having different size breasts. Nordvik fails to disclose the fluid flow path including an inflow line and an outflow line for placing the bladders in fluid communication with the reservoir nor a movable wall such that the fluid in the system can be moved by application of external pressure to the moveable wall. However, Neilson et al. discloses a closed loop system including an inflow line (94A) and an outflow line (96A) for placing a bladder in fluid communication with a compressible reservoir (110; Col. 8, line 40) and being free of a pump, wherein the closed loop system can be operated and removed without exposing a fluid within the closed loop system to the outside of the closed loop system (Col. 6, lines 15 – 20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the closed loop system as disclosed by Nordvik to include an inflow line and an outflow line, a compressible container and to be free of a pump, wherein the closed loop system can be operated and removed without exposing a fluid within the closed loop system to the outside of the closed loop system as taught by Neilson et al. in order to allow the closed loop system to be disposable to thereby eliminate otherwise necessary cleaning and sterilization of non-disposable, fixed heat transfer units (Col. 6, lines 15 – 20).

5. Claims 5, 17 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,273,868 to Nordvik in view of US Patent No. 5,733,319 to Neilson et al.

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Nordvik in view of Neilson et al. disclose a plurality of inflatable bladders, but fail to disclose at least 6 inflatable bladders. However, duplicating the components of a prior art device is a design consideration within the skill of the art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Response to Arguments

6. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736